



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

92084d

November 8, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER
CHI-7-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eung Chul Kim, President
Kimball Foods, Inc
3445 N. Kimball Ave.
Chicago, IL 60618-5516

Dear Mr Kim:

An investigator from the Food and Drug Administration conducted an inspection at your seafood processing facility on September 24, 25, and 26, 2001

The inspection found that you have serious deviations from the seafood HACCP (Hazard Analysis Critical Control Point) regulations (Title 21, Code of Federal Regulations (CFR), Part 123). These deviations, some of which were previously brought to your attention, cause the mackerel products prepared, packed, or held at your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You have no HACCP plan for unfrozen mackerel that you process. You must have a HACCP plan to control any food safety hazard(s) that are reasonably likely to occur. However, your firm does not have a HACCP plan for mackerel to control the food safety hazard of histamines

There are intervals during which monitoring records (temperature/ice) are not kept. For instance, there are intervals exceeding 2 days at times with no assurance products did not exceed critical limits for scombrototoxin formation.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

You should have your process, procedures, and necessary documents examined by a qualified Seafood HACCP individual to determine the HACCP requirements for scombrototoxin fish so that steps can be taken to develop a plan and perform the necessary HACCP operations to be in compliance with 21 CFR Part 123. It is essential that you respond to this office concerning this matter within 15 days of receipt of this letter, stating the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 30 days, state the reasons for the delay and the time at which the corrections will be completed.

Your reply should be directed to Paul Boehmer, Compliance Officer, at the above address.

Sincerely,

\s\
Raymond V. Mlecko
District Director